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Ltd.*

**IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP, KBI INC.,
and KBI-E INC.,

Plaintiffs and
Counterclaim Defendants,

v.

HANMI USA, INC., HANMI
PHARMACEUTICAL CO., LTD., HANMI
FINE CHEMICAL CO., LTD, and HANMI
HOLDINGS CO., LTD.,

Defendants and
Counterclaim Plaintiffs.

Civil Action No. 11-760 (JAP)(TJB)

**Hanmi's Motion in Limine No. 5
(To Preclude Testimony Of Dr. Paul Bartlett As To The State Of The Art Regarding
Gastric Acid Related Diseases)**

Hanmi hereby moves *in limine* to preclude the testimony of Dr. Paul Bartlett regarding the state of the art of with respect to gastric acid related diseases, methods of inhibiting gastric acid secretion and gastric acid secretion inhibitors (collectively referred to herein as “gastric acid related diseases”) in 1993, and regarding any opinions or views of a person of ordinary skill in the art regarding these areas in the 1993 timeframe – sections VII (¶¶ 94-122), VIII (¶¶ 123-144) and IX-X (¶¶ 145-174) of his report (Ex. 6).¹

Dr. Bartlett lacks sufficient qualifications to testify about the state of the art of gastric acid related diseases in 1993 (or even today), including the knowledge of a person of ordinary skill and the research activities of companies back in that timeframe. For these reasons, he should be precluded from testifying at trial concerning any matters related to these topics.

A. Background Facts

For most of his career – from 1973 until his retirement in 2003 – Dr. Bartlett performed no projects related to the development of a drug, much less any that focused on gastric acid related diseases. *See* Ex. 21, April 17, 2013 Deposition Transcript of Dr. Paul Bartlett, at pg. 14. In the summer of 1971, he worked for Sterling Winthrop, but he did not work on compounds related to the treatment of gastric acid related diseases. *Id.* at pp. 11, 13. None of the cases he has worked on in the last four years (listed on his CV) related to the gastric acid related drugs. (*Id.* at 17.) He does not recall having consulted on proton pump inhibitors (*id.* at 54-55), the class of drugs involved in this case. Of the approximately 180 articles on his publication list, none relate to drugs used in the treatment of gastric acid related diseases. He has never authored

¹ Hanmi only seeks to preclude Dr. Bartlett’s testimony concerning the state of the art with respect to gastric acid related diseases and a person of ordinary skill’s understanding of the same during the relevant timeframe. Hanmi does not seek to preclude the entirety of Dr. Bartlett’s testimony. The same sections of Dr. Bartlett’s testimony sought to be excluded herein are also the partial subject of Hanmi’s Motion *In Limine* No. 2 because they are new theories not in AstraZeneca’s contentions.

a publication related to proton pump inhibitors generally, or omeprazole or esomeprazole in particular. (*Id.* at 58.)

Although his expert report opines on many classes of compounds related to treating gastric acid related disorders, Dr. Bartlett conceded that the information in this section was provided to him by counsel in conjunction with another of AstraZeneca's experts, Dr. Johnson:

Q. Dr. Bartlett, beginning on page 31 of your report, you have a section called "State of the art for treatment of gastric acid-related disorders." If I could direct your attention to that portion of your report.

A. Okay.

Q. I'd like to know where you got the information for explaining of state of the art that you describe in this section of the report.

A. Well, this information came from counsel ultimately relying, as I point out here, on Dr. Johnson's report because he's detailing, I think, these areas that were in use or being investigated or followed at the time for treating disease. So I'm relying on Dr. Johnson for a lot of -- of this.

(*Id.* at 56.) Repeatedly, Dr. Bartlett confirmed that the information he relied upon for his report pertaining to the state of the art of gastric acid related diseases was provided largely by counsel or obtained indirectly from Dr. Johnson. (*Id.* at pp. 61; 65-66; 75; 77; 79; 80-81.)

Dr. Bartlett never spoke with anyone (other than counsel) to inform his views about the state of the art of the treatment of gastric acid related diseases:

Q. Okay. Did you speak to anyone who informed your views with respect to the state of the art of the treatment of gastric acid related diseases other than counsel?

A. I did not.

(*Id.* at 57.) Importantly, Dr. Bartlett never spoke with Dr. Johnson. (*Id.* at 62; 76.) For many of the compounds Dr. Bartlett depicted as illustrative of the classes of gastric acid related diseases, Dr. Bartlett was unaware if many of them had been approved by the FDA, or commercialized.

(*Id.* at 59; 60; 62; 73; 78; 80; 82.) Nor was Dr. Bartlett aware of their activity. (*Id.* at 73; 74; 82.)

Dr. Bartlett purported to opine on work done at AstraZeneca, but his sole sources of information were several documents provided to him by counsel. (*Id.* at 164-65.) Dr. Bartlett

did not independently conduct any search to inform his views as to the research being done at AstraZeneca (*id.* at 149-150), nor did he speak with anyone at AstraZeneca to inform his views. Dr. Bartlett also purported to opine on the research efforts at Byk Gulden, but the sole basis of his information was provided to him by counsel in the form of a declaration prepared by a Byk Gulden employee. Dr. Bartlett did not rely on anything else. Nor did he speak with any one at Byk Gulden (*id.* at pp. 184; 188-89). Thus, the substance of section VIII of his report should be excluded.

Dr. Bartlett admitted he is not an expert in the pharmacokinetics and pharmacodynamics of proton pump inhibitors (the class of drugs to which esomeprazole belongs) (*id.* at 100); nor is he an expert with regards to the clinical use of omeprazole or its pharmacology with respect to toxicity. (*Id.* at 101.) Although Dr. Bartlett eagerly concluded in his report that no motivation existed in 1993 to separate omeprazole's enantiomers, he was unable to comment on the motivation supplied by certain FDA articles and guidelines, and stated he had no opinion on their impact to a person of ordinary skill in the art. (*Id.* at 122.)

Dr. Bartlett is a chemist, but that does not qualify him to opine on the state of the art of gastric acid related drugs in 1993, persons of skill working in that field, or what those persons would have known.

B. Argument

The rules of evidence and case law make clear that in order to be qualified to opine as an expert in a field, the witness must actually have experience in the field itself, not simply familiarity with the field as a salesperson (or marketing executive). Under Fed. Rule Evid. 702, testimony is admissible only if it is both relevant and reliable. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999). Only witnesses who are "qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise."

Rule 702. The Rule “establishes a standard of evidentiary reliability” and “requires a valid . . . connection to the pertinent inquiry as a precondition to admissibility. 526 U.S. at 149 (quoting *Daubert v. Merrell Dow Pharmas., Inc.*, 509 U.S. 579, 590, 592 (1993)). And “where such testimony’s factual basis, data, principles, methods, or their application are called sufficiently into question, . . . the trial judge must determine whether the testimony has ‘a reliable basis in the knowledge and experience of [the relevant] discipline.’” *Kumho* at 149 (quoting *Daubert*, 509 U.S. at 592).

In *Aloe Coal v. Clark Equip. Co*, 816 F.2d 110 (Fed. Cir. 1987), the purchaser of a tractor shovel brought a negligence action against the manufacturer to recover its losses when the product was destroyed by a fire. 816 F.2d at 112. To show causation, the plaintiff relied solely on the expert testimony of a sales representative from another company whose position happened to acquaint him with the repair and replacement of damaged equipment. The Federal Circuit held that the district court had abused its discretion by allowing the witness to testify as an expert. Specifically, the Court explained that the proffered expert “was not an engineer” and “had no experience in designing construction machinery.” Further, he had “no knowledge or experience in determining the cause of equipment fires,” “no training as a mechanic,” and had “never operated construction machinery in the course of business.” In short, “[h]e was a salesman, who at times prepared damage estimates.” 816 F.2d at 114 -115.

Like the expert rejected by the court in *Aloe Coal*, Dr. Bartlett has no special knowledge or expertise on the state of the art of gastric acid related disease drugs in 1993, persons of skill working in that field, or what those persons would have known. He never worked in the field, never published in the field, never lectured in the field, never made a related drug, spoke to no one other than counsel to inform his views, and relied largely on materials provided to him by counsel.

In short, Dr. Bartlett is a chemist but admittedly lacks knowledge of the state of the art of with respect to gastric acid related diseases during the relevant timeframe, and is thus, not qualified to offer opinions concerning anything to do with gastric acid related diseases and particularly, the state of the art in 1993, and what a person of ordinary skill in the art would have known, believed or expected with respect to the same at this time.

Dr. Bartlett's testimony on this subject matter (sections VII-X of his report) should be precluded at trial for at least the reasons stated above.

Dated: April 29, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2013, I caused a copy of the foregoing **Hanmi's Motion in Limine No. 5 (To Preclude Testimony Of Dr. Paul Bartlett As To The State Of The Art Regarding Gastric Acid Related Diseases)** to be served upon the following counsel by electronic mail:

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